K020110

Boston Scientific
MICROVASIVE

APR 0 3 2002

Microvasive Urology
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508-650-8000
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III. Summary of Safety and Effectiveness

510(k) Summary for Surgical Mesh

A. Sponsor
Boston Scientific/ Urology
1 Boston Scientific Place
Natick, MA 01760

B. Contact
Lorraine M. Hanley
Director, Global Regulatory Affairs
Boston Scientific/ Urology
Telephone Number: (508) 650-8172
Fascimile: (508) 650-8144

C. Device Name
Surgical Mesh

D. Predicate Device(s)
Devices Classified per 21CFR 878.3300 as Class II, procode FTL
Tension Free Vaginal Tape (TVT): 510(k) K974098
Trelex® Mesh: 510(k) K945377
BioSling Bioabsorbable Polymer Sling and Surgical Mesh: 510(k) K010533
Suspend Sling: 510(k) K980483

E. Device Description
The Surgical Mesh is a knitted polypropylene monofilament fiber mesh, and may be offered in a variety of sizes and shapes for use in surgical repair procedures and for use as a pubovaginal sling. The surgical mesh may be offered with other legally marketed devices as a convenience to the user and to facilitate device placement such as with the proposed sling configuration, which includes the knitted polymer mesh within a protective sleeve for attachment to a delivery device

F. **Intended Use**
The proposed device is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension

G. Substantial Equivalence
The proposed device is substantially equivalent to the predicate devices previously classified under 21CFR 878.3300 as Class II, mesh, surgical, polymeric, procode FTL, in terms of its intended use; and the results of performance and biocompatibility testing demonstrate that the modifications proposed herein do not adversely effect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lorraine M. Hanley
Director
Global Regulatory Affairs
Boston Scientific/Urology
One Boston Scientific Place
Natick, Massachusetts 01760-1537

APR 0 3 2002

Re: K020110
Trade Name: Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: II
Product Code: FTL
Dated: January 9, 2002
Received: January 11, 2002

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use Statement

510(k) Number (if Known): K020110

Device Name: Surgical Mesh

Indications For Use:

It is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use (Optional Format 1-2-96)**

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020110